

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION

This document relates to:

All Cases Not Designated In  
Paragraphs 2 or 3 of CMO-1

MDL No. 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

**PLAINTIFFS' MOTION**  
**FOR MODIFICATION OF CMO 1**  
**REGARDING ARCOS MARKET SHARE**  
**DATA AND AMENDING COMPLAINTS**

Plaintiffs respectfully request that the Court enter the attached Proposed Revised Order (attached as Exhibit A), the purpose of which is to allow dissemination of market share information from the ARCOS data to the MDL Plaintiffs, subject to all recipients executing the ARCOS protective order, and to extend the time for the MDL Plaintiffs to amend complaints.

The PEC has consistently argued the nationwide ARCOS data should be made public and/or provided to each of the MDL Plaintiffs. On July 13, 2018, the Court entered an Order Regarding Plaintiffs' Motion for Modification of CMO-1 (Doc. 739) ("July Order"), which permitted the PEC to file a report derived from the ARCOS data identifying the entities that manufactured, distributed, or sold opioids in each county across the country; but the July Order precluded the report from disclosing any data.

The July Order required amended complaints utilizing the information contained in the report to be filed by November 16, 2018 (120 days from the PEC's filing of the report).

The unintended consequence of the PEC report will be the naming of hundreds of additional defendants with *de minimus* market share in more than a thousand amended complaints. To resolve this issue, without running afoul of the Court's strict mandate to keep the nationwide ARCOS data confidential, the PEC proposed the following solution to the MDL Defendants:

- A. On or before November 19, 2018, the PEC shall make available to plaintiffs in the MDL, and subject to the recipient's execution of the ARCOS protective order, reports derived from the ARCOS data that list, for every county or county equivalent,<sup>1</sup> all manufacturers, distributors and pharmacies that manufactured, distributed or sold of the prescription opioids (as set forth in Doc. 859) distributed in that county;
- B. The reports shall be disseminated according to the procedures set out in the Amended Notice of ARCOS Disclosure. (Doc. 859);
- C. The reports provided by the PEC shall include (1) Manufacturer Reports reflecting the names of all labelers<sup>2</sup> (as identified by NDC code) who

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<sup>1</sup> There are about 3,007 counties and 137 county-equivalents in the United States.

<sup>2</sup> Labeler information was derived using the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration code for each drug and cross referencing against the Food and Drug Administration, National Drug Code Directory and list of NDC/NHRIC Labeler Codes. A list of NDC/NHRIC Labeler Codes is available at <https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm191017.htm>.

Food and Drug Administration, *National Drug Code Directory* available at:

<https://www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt>

<https://www.deadiversion.usdoj.gov/arcos/ndc/readme.txt>

Additionally, the ARCOS Registrant Handbook provides the following definitions relating to labeler: A packer/repacker is a registrant that packs a product into a container (i.e., packer) or repacks a product into different size containers, such as changing a package of 50 capsules to 5 packages of 10 capsules each. A labeler/relabeler is a registrant that affixes the original label to a product (i.e., labeler) or

manufactured and/or labeled more than five percent (5%) of the market share of opioids distributed in the relevant county in at least three of the nine years available in the ARCOS data; (2) Distributor Reports reflecting the name of each distributor who distributed more than five percent (5%) of the market share of opioids distributed in the relevant county in at least three of the nine years available in the ARCOS data; and (3) Pharmacy Reports reflecting all opioid shipments to each pharmacy in the relevant county; and

- D. Plaintiffs in MDL cases<sup>3</sup> may then use this information to amend their complaints,<sup>4</sup> and must do so on or before March 16, 2019 (that is, within 120 days from PEC's filing of the reports).<sup>5</sup>

The PEC submitted the proposed solution to the MDL Defendants seeking their agreement and the MDL Defendants refused. Ironically, each MDL Defendant now has complete access to the nationwide ARCOS data (Doc. 552) yet they continue to object to its disclosure to each of the MDL Plaintiffs. Moreover, the MDL Defendants now insist the PEC disclose all "suspicious orders" to all of the MDL Defendants further stripping away the confidential protections entered by the Court. The PEC continues to

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changes in any way the labeling on a product without affecting the product or its container (i.e., relabeler). The "relabel" term implies that the package size remains unchanged with changes being made only in brand name, NDC number, distributor, etc. ARCOS Registrant Handbook at 6-2, available at <https://www.deadiversion.usdoj.gov/arcos/handbook/full.pdf#search=arcos%20handbook>.

<sup>3</sup> The Proposed Revised Order applies only to those cases not designated in paragraphs 2 or 3 of CMO-1.

<sup>4</sup> The entities that manufactured, distributed, or sold opioids in "County Y" may not be exactly the same entities that manufactured, distributed, or sold opioids in "City X" that is located in "County Y." Because creating a more granular, city-level report would be extremely burdensome, the county-level report can serve as a reasonable approximation, allowing for a sufficiently accurate identification of appropriately named defendants. Amended complaints may then refer to the PEC's reports.

<sup>5</sup> The deadlines in this Proposed Revised Order would apply to cases transferred into this MDL as of the date of entry of this order. With respect to cases transferred into this MDL after the entry of this Proposed Revised Order, any amended complaints to be filed without seeking leave of Court would be required to be filed the later of March 16, 2019, the applicable deadline under Fed. R. Civ. Pro. 15(a)(1), or 90 days following transfer into this MDL.

believe the need for transparency outweighs any prejudice arising from disclosure of the nationwide ARCOS data to each of the MDL Plaintiffs.

WHEREFORE, Plaintiffs respectfully request that this Honorable Court grant Plaintiffs' Motion for Modification of CMO 1 Regarding ARCOS Market Share Data and Amending Complaints.

Dated: November 2, 2018

Respectfully submitted,

s/Peter H. Weinberger

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*Plaintiffs' Co-Liaison Counsel*

### **CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 2nd day of November 2018, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF Systems.

s/Peter H. Weinberger

Peter H. Weinberger

*Plaintiffs' Co-Liaison Counsel*